

**K192344 Sapphire NC Plus Coronary Dilatation Catheter**Sep 19, 2019  
21 days to decisionK192344 · Product code: **LOX** · Cardiovascular  
Source: <https://www.510kdatabase.net/k192344/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheters, Transluminal Coronary Angioplasty, Percutaneous (LOX)
Date received	Aug 29, 2019
Decision date	Sep 19, 2019
Days to decision	21 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Orbusneich Medical Trading, Inc.</b>
Location	Fort Lauderdale, FL, US
Contact	John Pazienza
510(k) history	7 submissions · 7 cleared · 2018-2020

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k192344/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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